Practitioner's Docket No. 700355-053462-US

That

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kaplan et al.

Application No.:

10/541,182

January 7, 2004

Group No.:

To be assigned

Examiner:

To be assigned

Customer No.: 50828

For:

Filed:

SILK FIBROIN MATERIALS AND USE THEREOF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a) and 1.10)

I hereby certify that this correspondence:

- 1. Certificate of Mailing (1 pg.);
- 2. Transmittal Form (1 pg.);
- 3. Information Disclosure Statement with Forms 08a and b (3 pp.);
- 4. COPY References A1-A4, B1, B2 and C1-C20; and
- 5. Return Receipt Postcard.

is on the date shown below being:

MAILING

X deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313.

Date: January 24, 2006

FACSIMILE

transmitted by facsimile to the Patent and Trademark Office.

Signature

Rebecca J. Goodwin

(type or print name of person certifying)

PE MAS	Application Number	10/541,18	82					
│ ^{∕O} TRÄNSMITTAL	Filing Date	January 7	7, 2004					
27 2000 EORM	First Named Inventor	David L.						
\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \	Art Unit							
A superior of the second secon	Examiner Name							
Total Number of Pages in This Submission 7	700355-0	53462						
ENC	LOSURES (Check all	that apply)						
Fee Attached Amendment/Reply After Final	Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocatio Change of Correspondence A		Appea of Appea (Appea	Illowance Communication to TC I Communication to Board eals and Interferences I Communication to TC I Notice, Brief, Reply Brief) etary Information Letter				
Extension of Time Request Express Abandonment Request X Information Disclosure Statement Certified Copy of Priority Document(s)	Terminal Disclaimer Request for Refund CD, Number of CD(s) Landscape Table on CD	. C . R 	Enclosure(s) (please Identify: of Mailing; Copy of A1-A4, B1, B2 and d Return Receipt Postcard					
Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53								
	F APPLICANT, ATTO	RNEY, OR	RAGENT					
Firm Name Nixon Peabody, LLP								
Signature								
Printed name David S. Resnick								
Date 1/2 4/06		Reg. No. 3	34,235					
1 / 2 7/0 4								
CERTIFIC	CERTIFICATE OF TRANSMISSION/MAILING							
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:								
Signature Phecce	- Hood							
Typed or printed name Rebecca J. Goodwin	VI		Date	01/24/2006				

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kaplan, et al.

Application N.F. Filed

10/541,182 January 7, 2004 Group No.: Examiner:

To be assigned To be assigned

Customer No.: 50828

For:

LK FIBROIN MATERIALS AND USE THEROF

CERTIFICATE OF MAILING (37 C.F.R. SECTION 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the united States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date

Rebecca J. Goodiwn

type or print name of person mailing paper)

(signature of person mailing paper)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- within three (3) months of the Filing Date or before the mailing date of the First X (1) Office Action on the merits; or
- within three months of the mailing date of the PCT International Search Report; or (2)
- after the period defined in (1) but before the mailing date of a Final Rejection or (3) Notice of Allowance, and the requisite Certification or fee under Rule 1.17(p), namely \$180.00, is included herein; or

3		Practitioner's Docket No. 700355-053462-US Information Disclosure Statement Filed January 24, 2006 Page 2 of 2					
	_	(4)	after the mailing date of a Final Rejection or Notice of Allowance but before the				
			payment of the Issue Fee, and the requisite Certification, petition, and petition fee are				
			included herein.				
		(5)	A copy of the International Search Report - Form PCT/ISA/210 is enclosed herewith				
		•	ally requested that each of the documents shown on the attached form(s) PTO-1449 be application. Copies of these documents (CHECK ONE):				
	<u>X</u>	are e	nclosed herewith; and				
		have	been cited in the parent application, and are thus not being resubmitted herein.				
	Earl	y examin	nation and allowance of the present application are respectfully solicited.				
			FEE AUTHORIZATION				
	Shor	uld any fo	ees associated with the submission of this document be required, the Commissioner is				
	authorized to	charge	the missing fee to our Deposit Account No. 50-0850. Any overpayments should be				
	credited to sa	aid Depo	sit Account.				
	Date:	1/24/	Respectfully submitted,				
	Customer No	o. 50828	David S. Resnick (Reg. 34,235)				
			NIXON PEABODY LLP				

100 Summer Street

Boston, MA 02110-2131 (617) 345-6057

700355-053462

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Inder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/PTO 40] **Application Number** 10/541,182 INFORMATION DISCLÓSURE **Riling Date** 01/07/2004 TATEMENT BY APPLICANT 1 2006 grst Named Inventor David L. Kaplan Xrt Unit **Examiner Name** (Use as many sheets as necessary)

Attorney Docket Number

U. S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (fl known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	Al	^{US-} 5171505	12/15/1992	Lock			
	A2	^{US-} 5252285	12/12/1993	Lock			
	A3	^{us-} 6110590	08/29/2000	Zarkoob, et al.			
	A4	^{US-} 2004/0224406 A1	11/11/2004	Altman, et al.			
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
	•	US-					
//////////////////////////////////////		US-	Name of the second seco				
		US-					
	·	US-					
	·	US-	<u></u>				

FOREIGN PATENT DOCUMENTS											
Examiner Initials*			No.1 MM-DD-YYYY		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages					
		Country Cod	e ³ Number ⁴ Kind Code ⁵ (if known)				or Relevant Figures Appear	⊬			
	B1	WO	01/54667	A1	08/02/2001	Smithkline Beecham Corporation	***************************************	L			
	B2	wo	01/80921	A2	11/01/2001	Emory University		L			
			ſ								
			••••••••••••••••••••••••					Γ			
***************************************	·····			••••••		• • • • • • • • • • • • • • • • • • • •	***************************************	Т			

Examiner	Date	
Signature	Considered	
-	1	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-05)

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Recordion Act of no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for f	orm 1449B/F 10712 F	Ala			Complete if Known	`
				Application Number	10/541,182	
INFOR	MATION D	ISCLO	SURE	Filing Date	01/07/2004	
STATE	MENT BY	APPLI	CANT	First Named Inventor	David L. Kaplan	
				Art Unit		
(Use as many sheets a	s necessary)		Examiner Name		
Sheet	1	of	2	Attorney Docket Number	700355-053462	

NON PATENT LITERATURE DOCUMENTS								
Examiner Initials*								
	Cl	ANTHANASIOU, ET AL., "Sterilization, toxicity, biocompatibility and clinical applications of polylactic acid/polyglycolic acid copolymers," Biomaterials, 1996, Vol. 17 (No.), p. 93-102,						
	C2	BOGNITZKI, ET AL., "Nanostructured Fibers via Electrospinning," Adv Mater, 2001, Vol. 13 (No. 1), p. 70-72,						
	C3	BOLAND, ET AL., "Electrospinning of Tissue Engineering Scaffolds," Polymeric Materials: Science & Engineering, 2001, Vol. 85 (No.), p. 51-52,						
:	C4	CATERSON, ET AL., "Three-dimensional cartilage formulation by bone marrow-derived cells seeded in polylactide/alginate amalgam," Biomed Mater Res, 2001, Vol. 57 (No.), p. 394-403,	••••••					
	C5	DAL PRA, ET AL., "Silk Fibron-Coated Three-Dimensional Polyurethane Scaffolds for Tissue Engineering: Interactions with Normal Human Fibroblasts," Tissue Engineering, 2003, Vol. 9 (No. 6), p. 1113-1121,	••••••					
	C6	DOSHI, ET AL., "Electronspinning Process and Applications of Electrospun Fibers," Journal of Electrostatics, 1995, Vol. 35 (No.), p. 151-160,						
	C7	HOLY, ET AL., "Use of a biomimetic strategy to engineer bone," J Biomed Mater Res, 2003, Vol. 65A (No.), p. 447-453,	•••••					
	C8	HUTMACHER, "Scaffolds in tissue engineering bone and cartilage," Biomaterials, 2000, Vol. 21 (No.), p. 2529-2543,						
	С9	JIN, ET AL., "Electrospinning Bombyx morl Silk with Poly(ethylene oxide)," Polymer Preprints (American Chemical Society, Division of Polymer Chemistry), 2002, Vol. 43 (No. 2), p. 743-744,	•••••••					
	C10	KARP, ET AL., "Fabrication of Precise Cylindrical Three-Dimensional Tissue Engineering Scaffolds for In Vitro and In Vivo Bone Engineering Applications," The Journal of Craniofacial Surgery, 2003, Vol. 14 (No. 3), p. 317-323,	•••••					

		i ·
Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-05)

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1998, no persons are resided to respond to a collection of information unless it contains a valid OMB control number.

_		,		To Take Of the Control of the Contro	, 		
	Substitute for	r form 1449B/PTO	~	TOP FRANCE		Complete if Known	
					Application Number	10/541,182	
	INFO	RMATION DI	SCLO	SURE	Filing Date	01/07/2004	
	STAT	EMENT BY	APPLI	CANT	First Named Inventor	David L. Kaplan	
					Art Unit		
		(Use as many sheets as	necessary		Examiner Name		
	Sheet	2	of	2	Attorney Docket Number	700355-053462	フ

NON PATENT LITERATURE DOCUMENTS									
Examiner Initials*	TONG I TONG I TONG TO THE TONG TO THE TONG THE T								
	C11	LI, ET AL., "Study on Porous Silk Fibroin Materials. I. Fine Structure of Freeze Dried Silk Fibroin," J Appl Polym Sci, 2001, Vol. 79 (No.), p. 2185-2191,							
	C12	MARTIN, ET AL., "Selective differentiation of mammalian bone marrow stromal cells cultured on three-dimensional polymer foams," J Biomed Mater Res, 2001, Vol. 55 (No.), p. 229-235,							
	C13	NAM, ET AL., "Morphology of Regenerated Silk Fibroin: Effects of Freezing Termperature, Alcohol Addition, and Molecular Weight," J Appl Polym Sci, 2001, Vol. 81 (No.), p. 3008-3021,							
	C14	OHGUSHI, ET AL., "Calcium Phosphate Block Ceramic With Bone Marrow Cells in a Rat Long Bone Defect," CRC Handbook of Bioactive Ceramics, Vol. II (No.), p. 235-238,							
***************************************	C15	PEREZ-RIGUEIRO, "Silkworm Silk as an Engineering Material," J Appl Plym Sci, 1998, Vol. 70 (No.), p. 2439-2447,							
	C16	PETITE, ET AL., "Tissue-engineered bone regeneration," Nature Biotechnology, 2000, Vol. 18 (No.), p. 959-963,							
	C17	SOFIA, ET AL., "Functionalized silk-based biomaterials for bone formation," J Biomed Mater Res, 2000, Vol. 54 (No.), p. 139-148,							
	C18	STITZEL, ET AL., "Aterial Smooth Muscle Cell Proliferation on a Novel Biomimicking, Biodegradable Vascular Graft Scaffold," J Biomater Appl, 2001, Vol. 16 (No.), p. 22-33,	•••••						
	C19	ZARKOOB, "Structure and Morphology of Regernated Silk Nano-Fibers Produced by Electrospinning," A Dissertation Presented to The Graduate Faculty of the University of Akron, August 1998,	•••••						
	C20	ZARKOOB, "Structure and Morphology of Nano Electrospun Silk Fibers," Polymer Preprints (American Chemical Society, Division of Polymer Chemistry), 1998, Vol. 39 (No. 2), p. 244-245,							

	Ì	
Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.